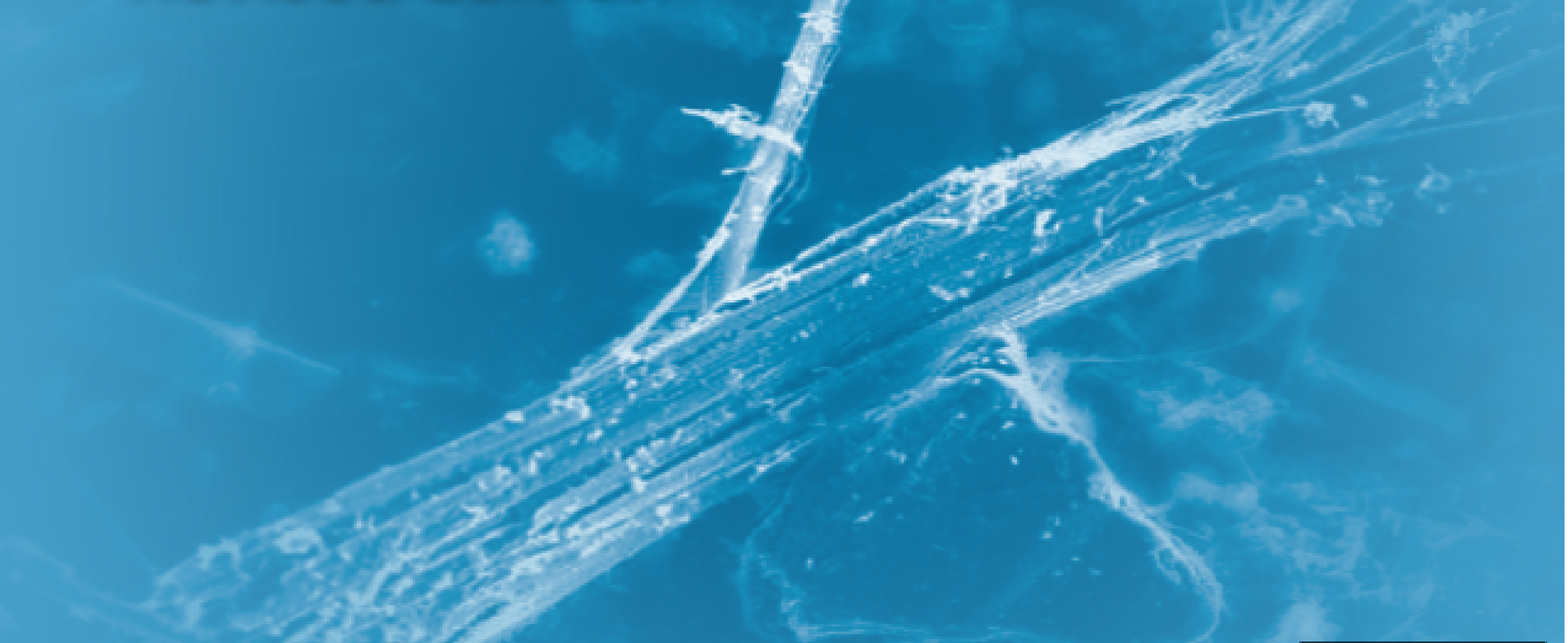
Exhibit 23

CURRENT INTELLIGENCE BULLETIN 62

Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research

Revised Edition



DEFENDANT'S EXHIBIT
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Cover Photograph: Transitional particle from upstate New York identified by the United States Geological Survey (USGS) as anthophyllite asbestos altering to talc. Photograph courtesy of USGS.

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April 2011

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Foreword

Asbestos has been a highly visible issue in public health for over three decades. During the mid- to late-20th century, many advances were made in the scientific understanding of worker health effects from exposure to asbestos fibers and other elongate mineral particles (EMPs). It is now well documented that asbestos fibers, when inhaled, can cause serious diseases in exposed workers. However, many questions and areas of confusion and scientific uncertainty remain.

The National Institute for Occupational Safety and Health (NIOSH) has determined that exposure to asbestos fibers causes cancer and asbestosis in humans on the basis of evidence of respiratory disease observed in workers exposed to asbestos, and recommends that exposures be reduced to the lowest feasible concentration. As the federal agency responsible for conducting research and making recommendations for the prevention of worker injury and illness, NIOSH has undertaken a reappraisal of how to ensure optimal protection of workers from exposure to asbestos fibers and other EMPs. As a first step in this effort, NIOSH convened an internal work group to develop a framework for future scientific research and policy development. The NIOSH Mineral Fibers Work Group prepared a first draft of this *State of the Science and Roadmap for Scientific Research (*herein referred to as the *Roadmap),* summarizing NIOSH's understanding of occupational exposure and toxicity issues concerning asbestos fibers and other EMPs.

NIOSH invited comments on the occupational health issues identified and the framework for research suggested in the first draft *Roadmap*. NIOSH sought other views about additional key issues that should be identified, additional research that should be conducted, and methods for conducting the research. In particular, NIOSH sought input from stakeholders concerning study designs, techniques for generating size-selected fibers, analytic approaches, sources of particular types of EMPs suitable for experimental studies, and worker populations suitable for epidemiological study. On the basis of comments received during the public and expert peer review process, NIOSH revised the *Roadmap* and invited public review of the revised version by stakeholders. After further revision and public comment, a revised draft *Roadmap* was submitted for review by the National Academies of Science in early 2009. Based on the National Academies assessment of the draft *Roadmap*, revisions were made, and NIOSH disseminated a fourth draft version of the document for final public comment in early 2010. After considering these comments, NIOSH has developed this final revision of the *Roadmap*.

The purpose of this *Roadmap* is to outline a research agenda that will guide the development of specific research programs and projects that will lead to a broader and

clearer understanding of the important determinants of toxicity for asbestos fibers and other EMPs. NIOSH recognizes that results from such research may impact environmental as well as occupational health policies and practices. Many of the issues that are important in the workplace are also important to communities and to the general population. Therefore, NIOSH envisions that the planning and conduct of the research will be a collaborative effort involving active participation of multiple federal agencies, including the Agency for Toxic Substances and Disease Registry (ATSDR), the Consumer Product Safety Commission (CPSC), the Environmental Protection Agency (EPA), the Mine Safety and Health Administration (MSHA), the National Institute of Environmental Health Sciences (NIEHS), the National Institute of Standards and Technology (NIST), the National Toxicology Program (NTP), the Occupational Safety and Health Administration (OSHA), and the United States Geological Survey (USGS), as well as labor, industry, academia, health and safety practitioners, and other interested parties, including international groups. This collaboration will help to focus the scope of the research, to fund and conduct the research, and to develop and disseminate informational materials describing research results and their implications for establishing new occupational and public health policies.

This *Roadmap* also includes a clarified rewording of the NIOSH recommended exposure limit (REL) for airborne asbestos fibers. This clarification is not intended to establish a new NIOSH occupational health policy for asbestos, and no regulatory response by OSHA or MSHA is requested or expected.

John Howard, MD
Director, National Institute for
Occupational Safety and Health
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Executive Summary

In the 1970s, NIOSH determined that exposure to asbestos fibers causes cancer and asbestosis in humans on the basis of evidence of respiratory disease observed in workers exposed to asbestos. Consequently, it made recommendations to the federal enforcement agencies on how to reduce workplace exposures. The enforcement agencies developed occupational regulatory definitions and standards for exposure to airborne asbestos fibers based on these recommendations. Since the promulgation of these standards, which apply to occupational exposures to the six commercially used asbestos minerals—the serpentine mineral chrysotile, and the amphibole minerals cummingtonite-grunerite asbestos (amosite), riebeckite asbestos (crocidolite), actinolite asbestos, anthophyllite asbestos, and tremolite asbestos—the use of asbestos in the United States has declined substantially and mining of asbestos in the United States ceased in 2002. Nevertheless, many asbestos products remain in use and new asbestos-containing products continue to be manufactured in or imported into the United States.

As more information became available on the relationship between the dimensions of asbestos fibers and their ability to cause nonmalignant respiratory disease and cancer, interest increased in exposure to other "mineral fibers." The term "mineral fiber" has been frequently used by nonmineralogists to encompass thoracic-size elongate mineral particles (EMPs) occurring either in an asbestiform habit (e.g., asbestos fibers) or in a nonasbestiform habit (e.g., as needle-like [acicular] or prismatic crystals), as well as EMPs that result from the crushing or fracturing of nonfibrous minerals (e.g., cleavage fragments). Asbestos fibers are clearly of substantial health concern. Further research is needed to better understand health risks associated with exposure to other thoracic-size EMPs, including those with mineralogical compositions identical or similar to the asbestos minerals and those that have already been documented to cause asbestos-like disease, as well as the physicochemical characteristics that determine their toxicity.

Imprecise terminology and mineralogical complexity have affected progress in research. "Asbestos" and "asbestiform" are two commonly used terms that lack mineralogical precision. "Asbestos" is a term used for certain minerals that have crystallized in a particular macroscopic habit with certain commercially useful properties. These properties are less obvious on microscopic scales, and so a different definition of asbestos may be necessary at the scale of the light microscope or electron microscope, involving characteristics such as chemical composition and crystallography. "Asbestiform" is a term applied to minerals with a macroscopic habit similar to that of asbestos. The lack of precision in these terms and the difficulty in translating macroscopic

properties to microscopically identifiable characteristics contribute to miscommunication and uncertainty in identifying toxicity associated with various forms of minerals. Deposits may have more than one mineral habit and transitional minerals may be present, which make it difficult to clearly and simply describe the mineralogy.

In 1990, NIOSH revised its recommendation concerning occupational exposure to airborne asbestos fibers. At issue were concerns about potential health risks associated with worker exposures to the analogs of the asbestos minerals that occur in a different habit—so-called cleavage fragments—and the inability of the analytical method routinely used for characterizing airborne exposures (i.e., phase contrast microscopy [PCM]) to differentiate nonasbestiform analogs from asbestos fibers on the basis of physical appearance. This problem was further compounded by the lack of more sensitive analytical methods that could distinguish asbestos fibers from other EMPs having the same elemental composition. To address these concerns and ensure that workers are protected, NIOSH defined "airborne asbestos fibers" to encompass not only fibers from the six previously listed asbestos minerals (chrysotile, crocidolite, amosite, anthophyllite asbestos, tremolite asbestos, and actinolite asbestos) but also EMPs from their nonasbestiform analogs. NIOSH retained the use of PCM for measuring airborne fiber concentrations and counting those EMPs having: (1) an aspect ratio of 3:1 or greater and (2) a length greater than 5 µm. NIOSH also retained its recommended exposure limit (REL) of 0.1 airborne asbestos fiber per cubic centimeter (f/cm^3).

Since 1990, several persistent concerns have been raised about the revised NIOSH recommendation. These concerns include the following:

- NIOSH's explicit inclusion of EMPs from nonasbestiform amphiboles in its 1990 revised definition of airborne asbestos fibers is based on inconclusive science and contrasts with the regulatory approach subsequently taken by OSHA and by MSHA.
- The revised definition of airborne asbestos fibers does not explicitly encompass EMPs from asbestiform amphiboles that formerly had been mineralogically defined as tremolite (e.g., winchite and richterite) or other asbestiform minerals that are known to be (e.g., erionite and fluoro-edenite) or may be (e.g., some forms of talc) associated with health effects similar to those caused by asbestos.
- The specified dimensional criteria (length and aspect ratio) for EMPs covered by the revised definition of airborne asbestos fibers may not be optimal for protecting the health of exposed workers because they are not based solely on health concerns.
- Other physicochemical parameters, such as durability and surface activity, may be important toxicological parameters but are not reflected in the revised definition of airborne asbestos fibers.
- NIOSH's use of the term "airborne asbestos fibers" to describe all airborne EMPs covered by the REL differs from the way mineralogists use the term and this inconsistency leads to confusion about the toxicity of EMPs.

NIOSH recognizes that its 1990 description of the particles covered by the REL for airborne asbestos fibers has created confusion, causing many to infer that the non-asbestiform minerals included in the NIOSH definition are "asbestos." Therefore, in this *Roadmap*, NIOSH makes clear that such nonasbestiform minerals are not "asbestos" or "asbestos minerals," and clarifies which particles are included in the REL. This clarification also provides a basis for a better understanding of the need for the proposed research. Clarification of the REL in this way does not change the existing NIOSH occupational health policy for asbestos, and no regulatory response by OSHA or MSHA is requested or expected. The REL remains subject to revision based on findings of ongoing and future research.

PCM, the primary method specified by NIOSH, OSHA, and MSHA for analysis of air samples for asbestos fibers, has several limitations, including limited ability to resolve very thin fibers and to differentiate various types of EMPs. Occupational exposure limits for asbestos derive from lung cancer risk estimates from exposure of workers to airborne asbestos fibers in commercial processes. These risk assessments are based on fiber concentrations determined from a combination of PCM-based fiber counts on membrane filter samples and fiber counts estimated from impinger samples. The standard PCM method counts only fibers longer than 5 µm. Moreover, some fibers longer than 5 µm may be too thin to be detected by PCM. Thus, an undetermined number of fibers collected on each sample remain uncounted by PCM. More sensitive analytical methods are currently available, but standardization and validation of these methods will be required before they can be recommended for routine analysis. However, unlike PCM, these methods are substantially more expensive, and field instruments are not available. In addition, any substantive change in analytical techniques used to evaluate exposures to asbestos and/or the criteria for determining exposure concentrations will necessitate a reassessment of current risk estimates, which are based on PCM-derived fiber concentrations.

Epidemiological evidence clearly indicates a causal relationship between exposure to fibers from the asbestos minerals and various adverse health outcomes, including asbestosis, lung cancer, and mesothelioma. However, NIOSH has viewed as inconclusive the results from epidemiological studies of workers exposed to EMPs from the nonasbestiform analogs of the asbestos minerals. Populations of interest for possible epidemiological studies include workers at talc mines in upstate New York and workers at taconite mines in northeastern Minnesota. Others include populations exposed to other EMPs, such as winchite and richterite fibers (asbestiform EMPs identified in vermiculite from a former mine near Libby, Montana), zeolites (such as asbestiform erionite), and other minerals (such as fluoro-edenite). Future studies should include detailed characterizations of the particles to which workers are or have been exposed.

There is considerable potential for experimental animal and *in vitro* studies to address specific scientific questions relating to the toxicity of EMPs. Short-term *in vivo* animal studies and *in vitro* studies have been conducted to examine cellular and tissue responses to EMPs, identify pathogenic mechanisms involved in those

responses, and understand morphological and/or physicochemical EMP properties controlling those mechanisms. Long-term studies of animals exposed to EMPs have been conducted to assess the risk for adverse health outcomes (primarily lung cancer, mesothelioma, and lung fibrosis) associated with various types and dimensions of EMPs. Such studies have produced evidence demonstrating the importance of dimensional characteristics of mineral particles for determining carcinogenic potential of durable EMPs. Although *in vitro* studies and animal studies are subject to uncertainties with respect to how their findings apply to humans, such studies are warranted to systematically assess and better understand the impacts of dimension, morphology, chemistry, and biopersistence of EMPs on malignant and nonmalignant respiratory disease outcomes.

To reduce existing scientific uncertainties and to help resolve current policy controversies, a strategic research program is needed that encompasses endeavors in toxicology, exposure assessment, epidemiology, mineralogy, and analytical methods. The findings of such research can contribute to the development of new policies for exposures to airborne asbestos fibers and other EMPs with recommendations for exposure indices that are not only more effective in protecting workers' health but firmly based on quantitative estimates of health risk. To bridge existing scientific uncertainties, this *Roadmap* proposes that interdisciplinary research address the following three strategic goals: (1) develop a broader and clearer understanding of the important determinants of toxicity for EMPs, (2) develop information on occupational exposures to various EMPs and health risks associated with such exposures, and (3) develop improved sampling and analytical methods for asbestos fibers and other EMPs.

Developing a broader and clearer understanding of the important determinants of toxicity for EMPs will involve building on what is known by systematically conducting *in vitro* studies and *in vivo* animal studies to ascertain which physical and chemical properties of EMPs influence their toxicity and their underlying mechanisms of action in causing disease. The *in vitro* studies could provide information on membranolytic, cytotoxic, and genotoxic activities as well as signaling mechanisms. The *in vivo* animal studies should involve a multispecies testing approach for short-term assays to develop information for designing chronic inhalation studies and to develop information on biomarkers and mechanisms of disease. Chronic animal inhalation studies are required to address the impacts of dimension, morphology, chemistry, and biopersistence on critical disease endpoints, including cancer and nonmalignant respiratory disease. Chronic inhalation studies should be designed to provide solid scientific evidence on which to base human risk assessments for a variety of EMPs. The results of toxicity studies should be assessed in the context of results of epidemiologic studies to provide a basis for understanding the human health effects of exposure to EMPs for which epidemiologic studies are not available.

Developing information and knowledge on occupational exposures to various EMPs and potential health outcomes will involve (1) collecting and analyzing available occupational exposure information to ascertain the characteristics and extent

of exposure to various types of EMPs; (2) collecting and analyzing available information on health outcomes associated with exposures to various types of EMPs; (3) conducting epidemiological studies of workers exposed to various types of EMPs to better define the association between exposure and health effects; and (4) developing and validating methods for screening, diagnosis, and secondary prevention for diseases caused by exposure to asbestos fibers and other EMPs.

Developing improved sampling and analytical methods for EMPs will involve (1) reducing interoperator and interlaboratory variability of currently used analytical methods; (2) developing a practical analytical method that will permit the counting, sizing, and identification of EMPs; (3) developing a practical analytical method that can assess the potential durability of EMPs as one determinant of biopersistence in the lung; and (4) developing and validating size-selective sampling methods for collecting and quantifying airborne thoracic-size asbestos fibers and other EMPs.

A primary anticipated outcome of the research that is broadly outlined in this *Roadmap* will be the identification of the physicochemical parameters such as chemical composition, dimensional attributes (e.g., ranges of length, width, and aspect ratio), and durability as predictors of biopersistence, as well as particle surface characteristics or activities (e.g., generation reactive oxygen species [ROS]) as determinants of toxicity of asbestos fibers and other EMPs. The results of the research will also help define the sampling and analytical methods that closely measure the important toxic characteristics and need to be developed. These results can then inform development of appropriate recommendations for worker protection.

Another outcome of the research that is broadly outlined in this *Roadmap* might be the development of criteria that could be used to predict, on the basis of results of *in vitro* testing and/or short-term *in vivo* testing, the potential risk associated with exposure to any particular type of EMP. This could reduce the need for comprehensive toxicity testing with long-term *in vivo* animal studies and/or epidemiological evaluation of each type of EMP. Ultimately, the results from such studies could be used to fill in knowledge gaps beyond EMPs to encompass predictions of relative toxicities and adverse health outcomes associated with exposure to other elongate particles (EPs), including inorganic and organic manufactured particles. A coherent risk management approach that fully incorporates an understanding of the toxicity of particles could then be developed to minimize the potential for disease in exposed individuals and populations.

This *Roadmap* is intended to outline the scientific and technical research issues that need to be addressed to ensure that workers are optimally protected from health risks posed by exposures to asbestos fibers and other EMPs. Achievement of the research goals framed in this *Roadmap* will require a significant investment of time, scientific talent, and resources by NIOSH and others. This investment, however, can result in a sound scientific basis for better occupational health protection policies for asbestos fibers and other EMPs.

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Abbreviations

8-OHdG	8-hydroxydeoxyguanosine
AED	aerodynamic equivalent diameter
AIHA	American Industrial Hygiene Association
AP-1	activator protein-1
ASTM	ASTM International [previously American Society for Testing and Materials]
ATSDR	Agency for Toxic Substances Disease Registry
BAL	bronchoalveolar lavage
BrdU	bromodeoxyuridine
CI	confidence interval
COX-2	cyclooxygenase-2
CPSC	Consumer Product Safety Commission
DM	dark-medium microscopy
DNA	deoxyribonucleic acid
DPPC	dipalmitoyl phosphatidylcholine
ED	electron diffraction
EDS	energy dispersive X-ray spectroscopy
EGFR	epidermal growth factor receptor
EM	electron microscopy
EMP	elongate mineral particle
EP	elongate particle
EPA	U.S. Environmental Protection Agency
ERK	extracellular signal-regulated kinase
ESR	electron spin resonance
f/cm^3	fibers per cubic centimeter
f/mL-yr	fibers per milliliter-year
HSL/ULO	Health and Safety Laboratory/UL Optics
ICD	International Classification of Diseases
IgG	immunoglobulin G
IL	interleukin
IMA	International Mineralogical Association
IMIS	Integrated Management Information System
IP	intraperitoneal
ISO	International Organization for Standardization
L	liter
LDH	lactate dehydrogenase
LOQ	limit of quantification
MDH	Minnesota Department of Health
mg/m^3-d	milligrams per cubic meter-days

MAPK	mitogen-activated protein kinase
MMAD	mass median aerodynamic diameter
MMMF	man-made mineral fiber
MMVF	man-made vitreous fiber
mppcf	million particles per cubic foot
MSHA	Mine Safety and Health Administration
mRNA	messenger ribonucleic acid
NADPH	nicotinamide adenine dinucleotide phosphate
NFκB	nuclear factor kappa beta
NIEHS	National Institute of Environmental Health Sciences
NMRD	nonmalignant respiratory disease
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NORA	National Occupational Research Agenda
NORMS	National Occupational Respiratory Mortality System
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PCMe	phase contrast microscopy equivalent
PCM	phase contrast microscopy
PEL	permissible exposure limit
RCF	refractory ceramic fiber
REL	recommended exposure limit
ROS	reactive oxygen species
RTV	RT Vanderbilt Company, Inc.
SAED	selected area X-ray diffraction
SEM	scanning electron microscopy
SMR	standardized mortality ratio
SO	superoxide anion
SOD	superoxide dismutase
SV40	simian virus 40
SVF	synthetic vitreous fiber
SWCNT	single-walled carbon nanotubes
TEM	transmission electron microscopy
TF	tissue factor
TGF	transforming growth factor
TNF-α	tumor necrosis factor-alpha
TWA	time-weighted average
USGS	United States Geological Survey
WHO	World Health Organization
XPS	X-ray photoelectron spectroscopy

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NIOSH greatly appreciates the time and efforts of expert peer reviewers who provided comments and suggestions on the initial publicly disseminated draft of the *Roadmap* (February 7, 2007 version).

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NIOSH appreciates the time and efforts of the National Academy of Sciences (NAS) committee members, consultant, and study staff who contributed to the development of the NAS report *A Review of the NIOSH Roadmap for Research on Asbestos Fibers and Other Elongate Mineral Particles* on the January 2009 version of the draft *Roadmap*. The individuals contributing to the report are identified in the NAS document.

Document History

Throughout its development, this *Roadmap* has undergone substantial public comment and scientific peer review with subsequent revision. All external input has been considered and addressed, as appropriate, to ultimately produce this final version of the *Roadmap*. A listing of the various draft versions disseminated for public comment and/or scientific peer review is presented here.

February 2007—Draft entitled *Asbestos and Other Mineral Fibers: A Roadmap for Scientific Research* was disseminated for public comment and scientific peer review.

June 2008—Draft entitled *Revised Draft NIOSH Current Intelligence Bulletin—Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research* was disseminated for public comment.

January 2009—Draft entitled *Revised Draft NIOSH Current Intelligence Bulletin—Asbestos Fibers and Other Elongated Mineral Particles: State of the Science and Roadmap for Research* was submitted to the Institute of Medicine and the National Research Council of the National Academies of Science for scientific review.

January 2010—Draft entitled *Draft NIOSH Current Intelligence Bulletin—Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research—Version 4* was disseminated for public comment.

March 2011—Final Version of *NIOSH Current Intelligence Bulletin—Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research* was published.

1 Introduction

Many workers are exposed to a broad spectrum of inhalable particles in their places of work. These particles vary in origin, size, shape, chemistry, and surface properties. Considerable research over many years has been undertaken to understand the potential health effects of these particles and the particle characteristics that are most important in conferring their toxicity. Elongate particles* (EPs) have been the subject of much research, and the major focus of research on EPs has related to asbestos fibers, a group of elongate mineral particles (EMPs) that have long been known to cause serious disease when inhaled. Because of the demonstrated health effects of asbestos, research attention has also been extended not only to other EMPs, but also to synthetic vitreous fibers which have dimensions similar to asbestos fibers and, more recently, to engineered carbon nanotubes and carbon nanofibers. Although nonmineral EPs are of interest, they are not the subject of this *Roadmap*, which focuses on EMPs.

Occupational health policies and associated federal regulations controlling occupational exposure to airborne asbestos fibers have been in existence for decades. Current regulations have been based on studies of the health effects of exposures encountered in the commercial exploitation and use of asbestos fibers. Nevertheless, important uncertainties remain to be resolved to fully inform possible revision of existing federal policies and/or development of new federal policies to protect workers from health effects caused by occupational exposure to airborne asbestos fibers.

Health effects caused by other exposures to EMPs have not been studied as thoroughly as health effects caused by exposures in the commercial exploitation and use of asbestos fibers. Miners and others exposed to asbestiform amphibole fibers associated with vermiculite from a mine near Libby, Montana, may not have been exposed to commercial asbestos fibers, but the adverse health outcomes they have experienced as a result of their exposure have indicated that those EMPs are similarly toxic. Other hardrock miner populations face uncertain but potential risk associated with exposures to EMPs that could be generated during mining and processing of nonasbestiform amphiboles. Studies of human populations exposed to airborne fibers of erionite, a fibrous mineral that is neither asbestos nor amphibole, have documented high rates of malignant mesothelioma (a cancer most commonly associated with exposure to asbestos fibers). Further research is warranted to understand how properties of EMPs determine toxicity so that the nature and magnitude of any potential toxicity associated with an EMP to which workers are exposed can be readily predicted and

*A glossary of technical terms is provided in Section 6. It includes definitions of terms from several standard sources in Tables 1 and 2. In general, where a term is used in this *Roadmap* the definitions in Tables 1 and 2 under the column "NIOSH 1990" are intended unless otherwise specified. Readers should be aware that, in reviewing publications cited in this *Roadmap*, it was not always possible to know the meaning of technical terms as used by the authors of those publications. Thus, some imprecision of terminology carries over into the literature review contained in this *Roadmap*.

controlled, even when exhaustive long-term studies of that particular EMP have not been carried out.

This *Roadmap* has been prepared and is being disseminated with the intent of motivating eventual development and implementation of a coordinated, interdisciplinary research program that can effectively address key remaining issues relating to health hazards associated with exposure to asbestos fibers and other EMPs.

Section 2, *Overview of Current Issues*, provides an overview of available scientific information and identifies important issues that need to be resolved before recommendations for occupational exposure to airborne asbestos fibers and related EMPs can be improved and before recommendations for occupational exposure to other EMPs can be developed. The nature of occupational exposures to asbestos has changed over the last several decades. Once dominated by chronic exposures in asbestos textile mills, friction product manufacturing, cement pipe fabrication, and insulation manufacture and installation, occupational exposures to asbestos in the United States now primarily occur during maintenance activities or remediation of buildings containing asbestos. OSHA has estimated that 1.3 million workers in general industry continue to be exposed to asbestos. In 2002 NIOSH estimated that about 44,000 mine workers might be exposed to asbestos fibers or amphibole cleavage fragments during the mining of some mineral commodities. These current occupational exposure scenarios frequently involve short-term, intermittent exposures, and proportionately fewer long fibers than workers were exposed to in the past. The generally lower current exposures and predominance of short fibers give added significance to the question of whether or not there are thresholds for EMP exposure level and EMP length below which workers would incur no demonstrable risk of material health impairment. The large number of potentially exposed workers and these changed exposure scenarios also give rise to the need to better understand whether appropriate protection is provided by the current occupational exposure recommendations and regulations. In addition, limited information is currently available on exposures to, and health effects of, other EMPs.

Section 3, *Framework for Research*, provides a general framework for research needed to address the key issues. NIOSH envisions that this general framework will serve as a basis for a future interdisciplinary research program carried out by a variety of organizations to (1) elucidate exposures to EMPs, (2) identify any adverse health effects caused by these exposures, and (3) determine the influence of size, shape, and other physical and chemical characteristics of EMPs on human health. Findings from this research would provide a basis for determining which EMPs should be included in recommendations to protect workers from hazardous occupational exposures along with appropriate exposure limits. A fully informed strategy for prioritizing research on EMPs will be based on a systematic collection and evaluation of available information on occupational exposures to EMPs.

Section 4, *The Path Forward*, broadly outlines a proposed structure for development and oversight of a comprehensive, interdisciplinary research program. Key to this approach will be (1) the active involvement of stakeholders representing parties with differing views, (2) expert study groups specifying and guiding various components of the research program, and (3) a multidisciplinary group providing careful ongoing review and oversight to ensure relevance, coordination, and impact of the overall

research program. NIOSH does not intend this (or any other) section of this *Roadmap* to be prescriptive, so detailed research aims, specific research priorities, and funding considerations have intentionally not been specified. Rather, it is expected that these more detailed aspects of the program will be most effectively developed with collaborative input from scientists, policy experts, and managers from various agencies, as well as from other interested stakeholders.

2 Overview of Current Issues

2.1 Background

Prior to the 1970s, concern about the health effects of occupational exposure to airborne fibers was focused on six commercially exploited minerals termed "asbestos:" the serpentine mineral chrysotile and the amphibole minerals cummingtonite-grunerite asbestos (amosite), riebeckite asbestos (crocidolite), actinolite asbestos, anthophyllite asbestos, and tremolite asbestos. The realization that dimensional characteristics of asbestos fibers were important physical parameters in the initiation of respiratory disease led to studies of other elongate mineral particles (EMPs) of similar dimensions [Stanton et al. 1981].

To date, occupational health interest in EMPs other than asbestos fibers has been focused primarily on fibrous minerals exploited commercially (e.g., wollastonite, sepiolite, and attapulgite) and mineral commodities that contain (e.g., Libby vermiculite) or may contain (e.g., upstate New York talc) asbestiform minerals. Exposure to airborne thoracic-size EMPs generated from the crushing and fracturing of nonasbestiform amphibole minerals has also garnered substantial interest. The asbestos minerals, as well as other types of fibrous minerals, are typically associated with other minerals in geologic formations at various locations in the United States [Van Gosen 2007]. The biological significance of occupational exposure to airborne particles remains unknown for some of these minerals and can be difficult to ascertain, given the mixed and sporadic nature of exposure in many work environments and the general lack of well-characterized exposure information.

The complex and evolving terminology used to name and describe the various minerals from which airborne EMPs are generated has led to much confusion and uncertainty in scientific and lay discourse related to asbestos fibers and other EMPs. To help reduce such confusion and uncertainty about the content of this *Roadmap*, several new terms are used in this *Roadmap* and defined in the Glossary (Section 6). The Glossary also lists definitions from a variety of sources for many other mineralogical and other scientific terms used in this *Roadmap*. Definitions from these sources often vary, and many demonstrate a lack of standardization and sometimes rigor that should be addressed by the scientific community.

To address current controversies and uncertainties concerning exposure assessment and health effects relating to asbestos fibers and other EMPs, strategic research endeavors are needed in toxicology, exposure assessment, epidemiology, mineralogy, and analytical methods. The results of such research might inform new risk assessments and the potential development of new policies for asbestos fibers and other EMPs, with recommendations for exposure limits that are firmly based on well-established risk estimates and that effectively protect workers' health. To support the development of these policies, efforts are needed to establish a common set of mineral terms that unambiguously describe EMPs and are relevant for toxicological assessments. What follows in the remainder of Section 2 is an overview of (1) definitions and terms relevant to asbestos fibers and other EMPs; (2) trends in

production and use of asbestos; (3) occupational exposures to asbestos and asbestos-related diseases; (4) sampling and analytical issues; and (5) physicochemical properties associated with EMP toxicity.

2.2 Minerals and Mineral Morphology

Minerals are naturally occurring inorganic compounds with a specific crystalline structure and elemental composition. Asbestos is a term applied to several silicate minerals from the serpentine and amphibole groups that occur in a particular type of fibrous habit and have properties that have made them commercially valuable. The fibers of all varieties of asbestos are long, thin, and usually flexible when separated. One variety of asbestos, chrysotile, is a mineral in the serpentine group of sheet silicates. Five varieties of asbestos are minerals in the amphibole group of double-chain silicates—riebeckite asbestos (crocidolite), cummingtonite-grunerite asbestos (amosite), anthophyllite asbestos, tremolite asbestos, and actinolite asbestos [Virta 2002].

Although a large amount of health information has been generated on workers occupationally exposed to asbestos, limited mineral characterization information and the use of nonmineralogical names for asbestos have resulted in uncertainty and confusion about the specific nature of exposures described in many published studies. Trade names for mined asbestos minerals predated the development of rigorous scientific nomenclature. For example, amosite is the trade name for asbestiform cummingtonite-grunerite and crocidolite is the trade name for asbestiform riebeckite. A changing mineralogical nomenclature for amphiboles has also contributed to uncertainty in the specific identification of minerals reported in the literature. Over the past 50 years, several systems for naming amphibole minerals have been used. The current mineralogical nomenclature was unified by the International Mineralogical Association (IMA) under a single system in 1978 [Leake 1978] and later modified in 1997 [Leake et al. 1997]. For some amphibole minerals, the name assigned under the 1997 IMA system is different than the name used prior to 1978, but the mineral names specified in regulations have not been updated to correlate with the new IMA system names.

Adding to the complexity of the nomenclature, serpentine and amphibole minerals typically develop through the alteration of other minerals. Consequently, they may exist as partially altered minerals having variations in elemental compositions. For example, the microscopic analysis of an elongate amphibole particle using energy dispersive X-ray spectroscopy (EDS) can reveal variations in elemental composition along the particle's length, making it difficult to identify the particle as a single specific amphibole mineral. In addition, a mineral may occur in different growth forms, or "habits," so different particles may have different morphologies. However, because they share the same range of elemental composition and chemical structure and belong to the same crystal system, they are the same mineral. Different habits are not recognized as having different mineral names.

Mineral habit results from the environmental conditions present during a mineral's formation. The mineralogical terms applied to habits are generally descriptive (e.g., fibrous, asbestiform, massive, prismatic, acicular, asbestiform, tabular, and platy). Both asbestiform (a specific fibrous type) and nonasbestiform versions (i.e., analogs) of the same mineral can occur in

juxtaposition or matrixed together, so that both analogs of the same mineral can occur within a narrow geological formation.

The habits of amphibole minerals vary, from prismatic crystals of hornblende through prismatic or acicular crystals of riebeckite, actinolite, tremolite, and others, to asbestiform habits of grunerite (amosite), anthophyllite, tremolite-actinolite, and riebeckite (crocidolite). The prismatic and acicular crystal habits occur more commonly, and asbestiform habit is relatively rare. Some of the amphiboles, such as hornblendes, are not known to occur in an asbestiform habit. The asbestiform varieties range from finer (flexible) to coarser (more brittle) and often are found in a mixture of fine and coarse fibrils. In addition, properties vary—e.g., density of (010) defects—even within an apparently homogeneous specimen [Dorling and Zussman 1987].

In the scientific literature, the term "mineral fibers" has often been used to refer not only to particles that occur in an asbestiform habit but also to particles that occur in other fibrous habits or as needle-like (acicular) single crystals. The term "mineral fibers" has sometimes also encompassed other prismatic crystals and cleavage fragments that meet specified dimensional criteria. Cleavage fragments are generated by crushing and fracturing minerals, including the nonasbestiform analogs of the asbestos minerals. Although the substantial hazards of inhalational exposure to airborne asbestos fibers have been well documented, there is ongoing debate about whether exposure to thoracic-size EMPs (EMPs of a size that can enter the thoracic airways when inhaled) from nonasbestiform analogs of the asbestos minerals is also hazardous.

2.3 Terminology

The use of nonstandard terminology or terms with imprecise definitions when reporting studies makes it difficult to fully understand the implications of these studies or to compare the results to those of other studies. For the health community, this ultimately hampers research efforts, leads to ambiguity in exposure-response relationships, and could also lead to imprecise recommendations to protect human health. Terms are often interpreted differently between disciplines. The situation is complicated by further different usage of the same terms by stakeholders outside of the scientific community. NIOSH has carefully reviewed numerous resources and has not found any current reference for standard terminology and definitions in several disciplines that is complete and unambiguous. An earlier tabulation of asbestos-related terminology by the USGS demonstrated similar issues [Lowers and Meeker 2002]. The terms "asbestos" and "asbestiform" exemplify this issue. They are commonly used terms but lack mineralogical precision. "Asbestos" is a term used for certain minerals that have crystallized in a particular macroscopic habit with certain commercially useful properties. These properties are less obvious on microscopic scales, and so a different definition of "asbestos" may be necessary at the scale of the light microscope or electron microscope, involving characteristics such as chemical composition and crystallography. "Asbestiform" is a term applied to minerals with a macroscopic habit similar to that of asbestos. The lack of precision in these terms and the difficulty in translating macroscopic properties to microscopically identifiable characteristics contribute to miscommunication and uncertainty in identifying toxicity associated with various forms of minerals. Some deposits may contain more than one habit or transitional particles may be

present, which make it difficult to clearly and simply describe the mineralogy. Furthermore, the minerals included in the term asbestos vary between federal agencies and sometimes within an agency.

NIOSH supports the development of standard terminology and definitions relevant to the issues of asbestos and other EMPs that are based on objective criteria and are acceptable to the majority of scientists. NIOSH also supports the dissemination of standard terminology and definitions to the community of interested nonscientists and encourages adoption and use by this community. The need for the development and standardization of unambiguous terminology and definitions warrants a priority effort of the greater scientific community that should precede, or at least be concurrent with, further research efforts.

2.3.1 Mineralogical Definitions

The minerals of primary concern are the asbestiform minerals that have been regulated as asbestos (chrysotile, amosite,† crocidolite,‡ tremolite asbestos, actinolite asbestos, and anthophyllite asbestos). In addition, there is interest in closely related minerals to which workers might be exposed that (1) were not commercially used but would have been mineralogically identified as regulated asbestos minerals at the time the asbestos regulations were promulgated (e.g., asbestiform winchite and richterite); (2) are other asbestiform amphiboles (e.g., fluoro-edenite); (3) might resemble asbestos (e.g., fibrous antigorite); (4) are unrelated EMPs (e.g., the zeolites erionite and mordenite, fibrous talc, and the clay minerals sepiolite and palygorskite); and (5) are individual particles or fragments of the nonasbestiform analogs of asbestos minerals. Minerals are precisely defined by their chemical composition and crystallography. Ionic substitutions occur in minerals, especially for metal cations of similar ionic charge or size. Such substitution can result in an *isomorphous series* (also referred to as *solid-solution* or *mixed crystal*) consisting of minerals of varying composition between end-members with a specific chemical composition. The differences in chemical composition within an *isomorphous series* can result in different properties such as color and hardness, as well as differences in crystal properties by alteration of unit-cell dimensions. It is sometimes possible to differentiate mineral species on the basis of distinctive changes through an *isomorphous series*. However, in general, classification occurs by an arbitrary division based on chemistry, and this can be complicated by having multiple sites of possible substitution (e.g., in a specific mineral, calcium may exchange for magnesium in one position whereas sodium and potassium may be exchanged in another position). These allocations are open to reevaluation and reclassification over time (e.g., the mineral now named richterite was called soda-tremolite in pre-1978 IMA nomenclature).

When certain minerals were marketed or regulated as asbestos, the mineral names had definitions that might have been imprecise at the time and might have changed over time. In particular, the mineral name amosite was a commercial term for a mineral that was not well defined at first. The definitions of amosite in the *Dictionary of Mining, Mineral, and Related Terms* [USBOM 1996] and in the *Glossary of Geology* [American Geological Institute 2005] allow for the possibility that amosite might be anthophyllite asbestos, although it is now known to be a mineral in the cummingtonite-grunerite series. This is one source of confusion in the literature.

†Amosite is not recognized as a proper mineral name.
‡Crocidolite is not recognized as a proper mineral name.

A further source of confusion comes from the use of the geological terms for a mineral habit. Minerals of the same chemistry differing only in the expression of their crystallinity (e.g., massive, fibrous, asbestiform, or prismatic) are not differentiated in geology as independent species. Thus, tremolite in an asbestiform crystal habit is not given a separate name (either chemical or common) from tremolite in a massive habit. It has been suggested that crystals grown in an "asbestiform" habit can be distinguished by certain characteristics, such as parallel or radiating growth of very thin and elongate crystals that are to some degree flexible, the presence of bundles of fibrils, and, for amphiboles, a particular combination of twinning, stacking faults, and defects [Chisholm 1973]. The geological conditions necessary for the formation of asbestiform crystals are not as common as those that produce other crystal habits. These other habits may occur without any accompanying asbestiform crystals. However, amphibole asbestos may also include additional amphiboles that, if separated, are not asbestiform [Brown and Gunter 2003]. The mineralogical community uses many terms, including fibril, fiber, fibrous, acicular, needlelike, prismatic, and columnar, to denote crystals that are elongate. In contrast, in sedimentology, similar terms have been more narrowly defined with specific axial ratios.

Thus it is not clear, even from a single reference source, exactly what range of morphologies are described by these terms and the degree of overlap, if any. For example, the Dictionary of Mining, Mineral, and Related Terms defines fibril as "a single fiber, which cannot be separated into smaller components without losing its fibrous properties or appearance," but also defines a fiber as "the smallest single strand of asbestos or other fibrous material."

2.3.2 Other Terms and Definitions

Health-related professions also employ terminology that can be used imprecisely. For example, the terms "inhalable" and "respirable" have different meanings but are sometimes used interchangeably. Also, each of these terms is defined somewhat differently by various professional organizations and agencies. Particles can enter the human airways, but the aspiration efficiency, the degree of penetration to different parts of the airways, and the extent of deposition depend on particle aerodynamics, as well as on the geometry and flow dynamics within the airways. In addition to obvious differences between species (e.g., mouse, rat, dog, primate, human), there is a significant range of variation within a species based on, for example, age, sex, body mass, and work-rate. Thus, these terms may mean different things to a toxicologist engaging in animal inhalation experiments, an environmental specialist concerned with childhood exposure, and an industrial hygienist concerned with adult, mostly male, workers.

2.4 Trends in Asbestos Use, Occupational Exposures, and Disease

2.4.1 Trends in Asbestos Use

Over recent decades, mining and use of asbestos have declined in the United States. The mining of asbestos in the United States ceased in 2002. Consumption of raw asbestos continues to decline from a peak of 803,000 metric tons in 1973 [USGS 2006]. In 2006, 2000 metric tons of raw asbestos were imported, down from an estimated 35,000 metric tons in 1991 (see Figure 1) and a peak of 718,000 metric tons in 1973. Unlike information on the importation of raw asbestos, information is not

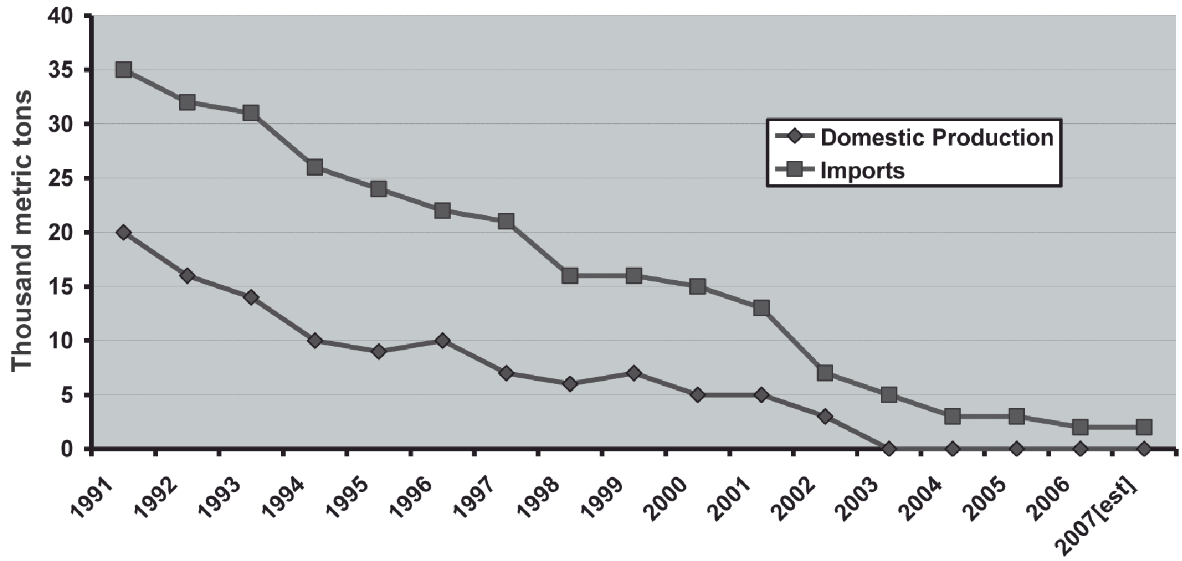

Figure 1. U.S. asbestos production and imports, 1991–2007. Source of data: USGS [2008].

readily available on the importation of asbestos-containing products. The primary recent uses for asbestos materials in the United States are estimated as 55% for roofing products, 26% for coatings and compounds, and 19% for other applications [USGS 2007], and more recently as 84% for roofing products and 16% for other applications [USGS 2008].

Worldwide, the use of asbestos has declined. Using the amount of asbestos mined as a surrogate for the amount used, worldwide annual use has declined from about 5 million metric tons in 1975 to about 2 million metric tons since 1999 [Taylor et al. 2006]. The European Union has banned imports and the use of asbestos with very limited exceptions. In other regions of the world, there is a continued demand for inexpensive, durable construction materials. Consequently, markets remain strong in some countries for asbestos-cement products, such as asbestos-cement panels for construction of buildings and asbestos-cement pipe for water-supply lines. Currently over 70% of all mined asbestos is used in Eastern Europe and Asia [Tossavainen 2005].

Historically, chrysotile accounted for more than 90% of the world's mined asbestos; it presently accounts for over 99% [Ross and Virta 2001; USGS 2008]. Mining of crocidolite (asbestiform riebeckite) and amosite (asbestiform cummingtonite-grunerite) deposits have accounted for most of the remaining asbestos. Mining of amosite is thought to have ceased in 1992 and mining of crocidolite is thought to have ended in 1997, although it is not possible to be certain. Small amounts of anthophyllite asbestos have been mined in Finland [Ross and Virta 2001] and are currently being mined in India [Ansari et al. 2007].

2.4.2 Trends in Occupational Exposure

Since 1986, the annual geometric mean concentrations of occupational exposures to asbestos in the United States, as reported in the Integrated Management Information System (IMIS) of the Occupational Safety and Health Administration

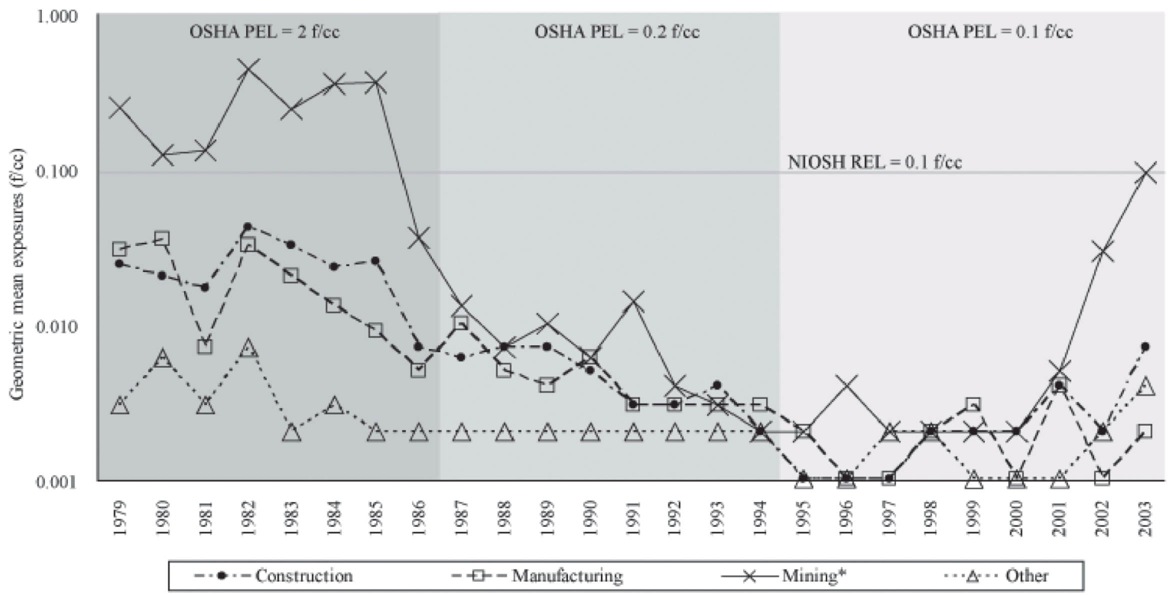

Figure 2. Asbestos: Annual geometric mean exposure concentrations by major industry division, MSHA and OSHA samples, 1979–2003. Source of data: NIOSH [2007a]. Note: the MSHA PEL for this time period was 2 f/cm^3.

(OSHA) and the database of the Mine Safety and Health Administration (MSHA), have been consistently below the NIOSH recommended exposure limit (REL) of 0.1 fibers per cubic centimeter of air (f/cm^3) for all major industry divisions (Figure 2). The number of occupational asbestos exposures that were measured and reported in IMIS decreased from an average of 890 per year during the 8-year period of 1987–1994 to 241 per year during the 5-year period of 1995–1999 and 135 for the 4-year period of 2000–2003. The percentage exceeding the NIOSH REL decreased from 6.3% in 1987–1994 to 0.9% in 1995–1999, but it increased to 4.3% in 2000–2003. During the same three periods, the number of exposures measured and reported in MSHA's database decreased from an average of 47 per year during 1987–1994 to an average of 23 per year during 1995–1999, but it increased to 84 during 2000–2003 (most of which were collected in 2000). The percentage exceeding the NIOSH REL decreased from 11.1% in 1987–1994 to 2.6% in 1995–1999, but it increased to 9.8% in 2000–2003 [NIOSH 2007a].

The preceding summary of occupational exposures to asbestos is based on the OSHA and MSHA regulatory definitions relating to asbestos. Because NIOSH includes nonasbestiform analogs of the asbestos minerals in the REL that may have, at least from some samples, been excluded by OSHA and MSHA in performing differential counting, the reported percentages of exposures exceeding the REL should be interpreted as lower limits. Because of analytical limitations of the phase contrast microscopy (PCM) method and the variety of workplaces from which the data were obtained, it is unclear what portions of these exposures were to EMPs from nonasbestiform analogs of the asbestos minerals, which have been explicitly encompassed by the NIOSH REL for airborne asbestos fibers since 1990.

Very limited information is available on the number of workers still exposed to asbestos. On the basis of mine employment data [MSHA 2002], NIOSH estimated that 44,000 miners and other mine workers may be exposed to asbestos or amphibole cleavage fragments during the mining of some mineral commodities [NIOSH 2002]. OSHA estimated in 1990 that about 568,000 workers in production and services industries and 114,000 in construction industries may be exposed to asbestos in the workplace [OSHA 1990]. More recently, OSHA has estimated that 1.3 million employees in construction and general industry face significant asbestos exposure on the job [OSHA 2008].

In addition to evidence from OSHA and MSHA that indicates a reduction in occupational exposures in the United States over the last several decades of the 1900s, other information compiled on workplace exposures to asbestos indicates that the nature of occupational exposures to asbestos has changed [Rice and Heineman 2003]. Once dominated by chronic exposures in manufacturing processes such as those used in textile mills, friction product manufacturing, and cement pipe fabrication, current occupational exposures to asbestos in the United States primarily occur during maintenance activities or remediation of buildings containing asbestos. These current occupational exposure scenarios frequently involve short-term, intermittent exposures.

2.4.3 Trends in Asbestos-related Disease

Evidence that asbestos causes lung cancer and mesothelioma in humans is well documented [NIOSH 1976; IARC 1977, 1987a,b; EPA 1986; ATSDR 2001; HHS 2005a]. Epidemiological studies of workers occupationally exposed to asbestos have clearly documented a substantial increase in risk of several nonmalignant respiratory diseases, including diffuse fibrosis of the lung (i.e., asbestosis) and nonmalignant pleural abnormalities including acute pleuritis and chronic diffuse and localized thickening of the pleura [ATS 2004]. In addition, it has been determined that laryngeal cancer [IOM 2006] and ovarian cancer [Straif et al. 2009] can be caused by exposure to asbestos, and evidence suggests that asbestos may also cause other diseases (e.g., pharyngeal, stomach, and colorectal cancers [IOM 2006] and immune disorders [ATSDR 2001]).

National surveillance data, showing trends over time, are available for two diseases with rather specific mineral fiber etiologies—asbestosis and malignant mesothelioma (see following subsections). Lung cancer is known to be caused in part by asbestos fiber exposure but has multiple etiologies. Ongoing national surveillance for lung cancer caused by asbestos exposure has not been done. However, using various assumptions and methods, several researchers have projected the number of U.S. lung cancer deaths caused by asbestos. Examples of the projected number of asbestos-caused lung cancer deaths in the United States include 55,100 [Walker et al. 1983] and 76,700 [Lilienfeld et al. 1988]; each of these projections represent the 30-year period from 1980 through 2009. However, in the absence of specific diagnostic criteria and a specific disease code for the subset of lung cancers caused by asbestos, ongoing surveillance cannot be done for lung cancer caused by asbestos.

2.4.3.1 Asbestosis

NIOSH has annually tracked U.S. deaths due to asbestosis since 1968 and deaths due to malignant mesothelioma since 1999, using death certificate data in the National Occupational Respiratory Mortality System (NORMS). NORMS